K092205

page 1 of 2

510(k) Summary

Date Summary Was Prepared: July 13, 2009

Submitter's Information:

Kendall,
a Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, MA 02048
Phone: 508-261-8000
Fax: 508-261-6644

OCT 30 2009

Contact:

Daniel Campion
Senior Regulatory Affairs Specialist
Kendall,
a Division of Tyco Healthcare Group LP
Telephone: 508-452-4135
Fax: 508-261-8461

Device Trade Name: Palindrome™ P Hemodialysis Catheter

Device Common Name: Catheter, Hemodialysis, Apheresis, Intravascular

Classification Panel: Gastroenterology

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
The Palindrome™ P Hemodialysis Catheter is substantially equivalent to the Kendall Palindrome™ 14.5 Fr Chronic Hemodialysis Catheter with Slotted Symmetrical Tip (K043272) in intended use, materials, physical characteristics, and performance characteristics. The insertion procedure of the catheter is equivalent to the predicate Arrow Cannon II Plus (K040078).

Device Description:
The Palindrome P Hemodialysis Catheter has a radiopaque polyurethane shaft with two large inner lumens designed in a "double D" configuration. The Catheter will be supplied with a detached connector assembly allowing for the catheter tip to be positioned in the vein and tunneled retrograde to the exit site. The hub and back end of the catheter is then assembled with a snap lock connector with compression ring.

A Palindrome™ Reverse Tunneled catheter repair kit will be offered to replace damaged extensions and / or extension adaptors.

Intended Use:
The Palindrome P Hemodialysis Catheter is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. Catheters greater than 40 cm implant length are indicated for femoral insertion.

The Palindrome P Catheter Repair Kit is indicated to repair the hub/back end assembly (extension tubing, luer adapter(s) or clamp(s)) or to repair the hub snap connector component(s) of the Palindrome P Hemodialysis Catheter

K092205
page 2 of 2

Performance Data:

Testing was performed to compare the proposed Palindrome™ P Reverse Tunneled Catheter to predicate device. Results of verification / validation demonstrate that the modified device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OCT 3 0 2009

Covidien
c/o Mr. Daniel Campion
Senior Regulatory Affairs Specialist
Kendall
a Division of Tyco Healthcare Group LP
15 Hampshire Street
MANSFIELD MA 02048

Re: K092205
Trade/Device Name: Palindrome™ P Reverse Tunneled Hemodialysis Catheter and Repair Kit
Regulation Number: 21 CFR §876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: III
Product Code: MSD, NFK
Dated: September 25, 2009
Received: September 29, 2009

Dear Mr. Campion:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. *Please note:* If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

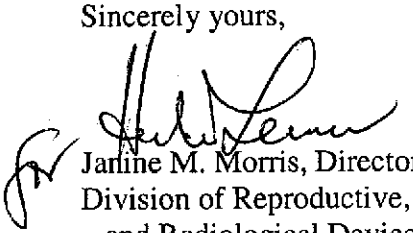
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris, Director (Acting)
Division of Reproductive, Abdominal,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K092205

Indications for Use Statement

Device Name:

Palindrome™ P Reverse Tunneled Hemodialysis Catheter and Repair Kit

Indications for Use:

The Palindrome Reverse Tunneled Catheter is intended for acute and chronic hemodialysis, apheresis, and infusion. It may be inserted either percutaneously or by cutdown. Catheters greater than 40 cm implant length are indicated for femoral insertion.

The Palindrome reverse-tunneled catheter repair kit is intended for the repair of the hub/back end assembly (extension tubing, luer adapter(s) or clamp(s)) or to repair the hub snap connector component(s). A repair can only be made if the tubing length between the hub snap connector and the exit sit is a minimum of 5.5 cm

Please Do Not Write Below This Line – Continue On Another Page If Needed

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092205